JUL 14 1999

Section 7- 510k Summary

K991500

7.1 Statement

This 510k summary is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

7.2 Submitter

Smith and Nephew, Inc.
Endoscopy Division
130 Forbes Boulevard
Mansfield, Ma. 02048

7.3 Company Contact

Sigi Caron
Regulatory Manager
(508) 261-3773

7.4 Device Name

Proprietary Name: Smith & Nephew Suture Collet

Common Name:

- Suture Retention Device,
- Endoscopic Accessory,
- Laparoscopic Accessory

Classification Name:

- Suture Retention Device (79 KGS)
- Endoscopic accessories (78 GCJ)
- Laparoscopic accessories (85 HET)

7.5 Predicate Legally Marketed Devices

- Suture Collet
- Suture Lock
- Smith & Nephew and Acufex MIS Instruments

7.6 Device Description

The Smith & Nephew Suture Lok comprises three main components:

- the suture Lok implant (ring and pin),
- the disposable cartridge assembly with threader, and
- the reusable delivery instrument.

7.7 Intended Use

The Smith & Nephew Suture Lok is intended for use in the management of soft vessel ligation and/or fixation of soft tissue structures during open and endoscopic procedures.

7.8 Device Indications

The Smith & Nephew Lok is indicated for use in endoscopic procedures, including thoracoscopic surgery and laparoscopic procedures.

7.9 Substantial Equivalence

The Smith & Nephew Suture Lok is substantially equivalent to the Suture Collet, the Suture Lock, and braided silk, nylon or polyester 0, 2-0, and 3-0 suture. Comparative strength testing demonstrates the equivalence of the Suture Lok to the predicate devices.

The table below summarizes the similarities of the two devices. The similarities in design, materials, intended use, and indications for use between the Smith & Nephew Suture Lok and the predicate devices support the claim of substantial equivalence.

	Suture Lok	**Suture Collet**
Implant:		
Product Labeling	Sterile: Single Use Only	Sterile: Single Use Only
Materials	Implant grade polyacetal	Implant grade polyacetal
Indications	Open and Endoscopic/Laparoscopic/Thoracoscopic Surgical Procedures	Open and Arthroscopic Surgical Procedures
Indicated for use with	0, 2-0 and 3-0 braided silk, nylon or polyester sutures	2-0 silk monofilament sutures
Intended Use	Management of Soft Tissue	Management of Soft Tissue
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Delivery Instrument		
Materials	Aluminum and Stainless Steel	Aluminum and Stainless Steel
Sterilization Method	Supplied non-sterile: must be sterilized prior to use via steam autoclave or ethylene oxide	Supplied non-sterile: must be sterilized prior to use via steam autoclave or ethylene oxide

Applicant_____ **Date**_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1999

Mr. Sigi Caron
Regulatory Manager
Smith & Nephew, Inc.
130 Forbes Boulevard
Mansfield, Massachusetts 02048

Re: K991500
Trade Name: Smith & Nephew Suture Lok
Regulatory Class: II
Product Code: KOG
Dated: April 28, 1999
Received: April 29, 1999

Dear Mr. Caron:

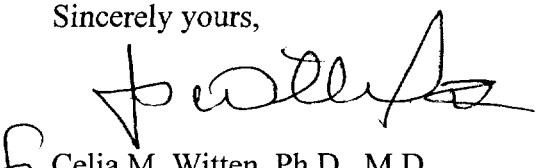
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if Known):

Device Name: Smith & Nephew Suture Lok

Indications For Use:

The Smith & Nephew Suture Lok is indicated for use in open and endoscopic procedures, including thoracoscopic surgery, laparoscopic procedures and general surgery. This device is not indicated for use in contraception tubal ligation.

Intended Use:
The Smith & Nephew Suture Lok is intended for use in conjunction with USP size 0 2-0 and 3-0 Braided silk, nylon or polyester non-absorbable sutures in the management of soft vessel ligation and/or fixation of soft tissue structures during open and endoscopic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use _____
(per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991500